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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,725	09/18/2003	Manabu Nakatani	1/1395US	4358

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EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,725	NAKATANI ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1-15 are examined.

Applicant has provided arguments for the patentability of claims 1-15 in the response filed 19 May 2006.

Applicant's arguments, see response, filed 19 May 2006, have been fully considered but are not persuasive. Any rejection not specifically stated in this Office Action has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Application No. 2005/0089575 to Friedl et al.

The applied reference may have a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Friedl et al. teach a bilayered (in current claim 13; see Title) pharmaceutical composition comprising from 3 to 50 wt % of telmisartan (in current claims 1-13; see paragraph 49), a basic agent such as NaOH and metal hydroxides (in current claims 2-3; see paragraph 46) wherein the ratio of telmisartan and basic agent are within the range of 1:1 to 1:10 (in current claim 1; see paragraph 49 such that the basic agent and active can be present in 10 wt for example), from 0.01 to 5 wt % surfactants (in current claim 1; see paragraph 58) wherein the surfactant includes Pluronic™ (poloxamers) (in current claims 4-6; see paragraph 63), water soluble diluent present in an amount of from 60-80 wt% (in current claim 1; see paragraph 49) such as glucose (in current claims 7-8; see paragraph 47), a diuretic (in current claim 13; see paragraph 34) and an additional excipient such as a binder (in current claim 9; see paragraph 61) wherein the composition is in the form of a tablet (in current claim 10; see Title) and further comprises a dosage unit of 10 to 160mg (in current claims 11-12; see paragraph 43).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application No. 2005/0089575 to Friedl et al.

Friedl et al. teach a bilayered (in current claim 13; see Title) pharmaceutical composition comprising from 3 to 50 wt % of telmisartan (in current claims 1-13; see paragraph 49), a basic agent such as NaOH and metal hydroxides (in current claims 2-3; see paragraph 46) wherein the ratio of telmisartan and basic agent are within the range of 1:1 to 1:10 (in current claim 1; see paragraph 49 such that the basic agent and active can be present in 10 wt for example), from 0.01 to 5 wt % surfactants (in current claim 1; see paragraph 58) wherein the surfactant includes Pluronic™ (poloxamers) (in

current claims 4-6; see paragraph 63), water soluble diluent present in an amount of from 60-80 wt% (in current claim 1; see paragraph 49) such as glucose (in current claims 7-8; see paragraph 47), a diuretic (in current claim 13; see paragraph 34) and an additional excipient such as a binder (in current claim 9; see paragraph 61) wherein the composition is in the form of a tablet (in current claim 10; see Title) and further comprises a dosage unit of 10 to 160mg (in current claims 11-12; see paragraph 43).

Additionally Friedl et al. teach a process for preparing telmisartan comprising preparing a granulation liquid (in current claim 14; see paragraph 115) or a spray solution and spray drying (in current claim 15; see paragraphs 99 and 101), mixing the granulate with a diluent and drying the granulation (in current claim 14; see paragraphs 74 and 115) and finally screening the granulate (in current claim 15; see paragraph 116).

Friedl et al. do not specifically recite the use of ethanol but one of ordinary skill in the art would appreciate the use of ethanol[1] as a solvent. Thus, the combined references teach and make prima facie obvious how to use the claimed invention at the time that it was made.

Response to Arguments - 35 USC § 102

Applicant's arguments filed 19 May 2006 have been fully considered but they are not persuasive. Applicant's argue that the amount of surfactant in the reference is different from the claimed amount. Examiner points out that although the ranges are

[1] ethanol. Crystal Reference Encyclopedia (2001). Retrieved 10 November 2005, from xreferplus. http://www.xreferplus.com/entry/931538

not exactly the same, there is an overlap at 1% and for that reason at least the rejection is maintained as proper.

Response to Arguments - 35 USC § 103

Applicant's arguments filed 19 May 2006 have been fully considered but they are not persuasive. Applicant argues that Friedl et al. teach spray-drying as the preferred manufacturing process. That said, claim 15 for example recites spray drying the aqueous spray solution (see (ii) of claim 15). To that end, the reference teaches the claim limitations and is a proper basis for rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

22 August 2006
MG

Ardin H. Marschel 8/27/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER